



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 12, 2018

Mr. John B. Baker
ZOETIS Inc.
333 Portage St.
Kalamazoo, MI 49007-4931

Subject: Label Amendment – PDCI-069001-26530 label changes
Product Name: DURASECT II
EPA Registration Number: 1007-91
Application Date: March 12, 2018
Decision Number: 541772

Dear Mr. Baker:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

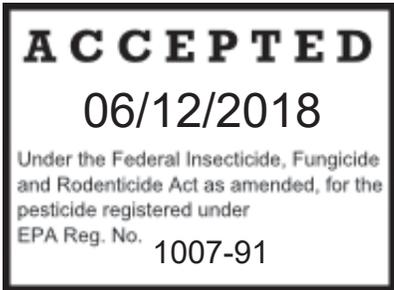
Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Helen Hull-Sanders by phone at 703-347-0243, or via email at hull-sanders.helen@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Elizabeth Fertich". The signature is cursive and somewhat stylized, with the first name being more prominent.

Elizabeth Fertich
Product Manager 04
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure



Master Label
(FRONT LABEL)

Durasect II

- Ready to use Pour-On for beef, lactating, and non-lactating dairy cattle and calves
- Effective in the control of pyrethroid-resistant horn-flies
- Up to 4-week control of horn flies⁺
- No withdrawal time
- Treats 60 500-lb cattle or 30 1000-lb cattle

Active Ingredients:

*Permethrin (3-phenoxyphenyl) methyl ±cis, trans-3-(2,2-dichloroethenyl)-2,2-dimethyl-cyclopropanecarboxylate.....	5.0%
Pyrethrins.....	0.1%
Piperonyl butoxide**.....	1.0%
Other Ingredients.....	93.9%
TOTAL.....	100.0%

*cis/trans ratio: Min 35%(±) *cis* and max 65% (±) *trans*

** (butyl carbityl)(6-propylpiperonyl) ether and related compounds

Keep Out of Reach of Children
CAUTION

See Back Panel for Precautionary Statements

Net Contents: 900 mL (30.43 fl. Oz.)

⁺Duration of activity for horn fly control may vary due to pyrethroid resistance, environment conditions and management factors (i.e., sanitation, animal husbandry, facilities, etc.)

Distributed by:
Zoetis Inc.
333 Portage Street
Kalamazoo, MI 49007

EPA Est. No.
EPA Reg. No. 1007-91

(BACK LABEL)

Directions for Use

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

- Except when applying to livestock, do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.
- When used in dairy barns or facilities: close milk bulk tank lids to prevent contamination from spray and from dead or falling insects. Remove or cover milk utensils before application. Wash teats of animals before milking.
- Do not make applications during rain.
- Not for use in metered release systems.

READY TO USE – No dilution necessary, see directions below.

Animal Treatments

Lactating and Non-lactating Dairy Cattle, Beef Cattle, and Calves

Target Insects: Controls Horn Flies

Application: Apply along back and down face. Use 0.1 fl oz (3 mL) per 100 lb (45 kg) of body weight of animal, up to 1 fl oz for any one animal.

Durasect II is to be applied with the squeeze-and-pour bottle provided. To use the squeeze-and-pour bottle, remove the cap and inner seal from the calibrated dosing chamber. Estimate the animal's weight and calculate the dose. Squeeze the bottle to fill the dosing chamber to the desired level. Apply product per directions above; do not use product as a spray. Repeat treatment as needed, but no more than once every 2 weeks.

Pesticide Storage and Disposal and Container Handling

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Keep container sealed when not in use. Do not store near food or feed.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of at an approved waste disposal facility.

Container Handling: Non-refillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

Environmental Hazards

This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash waters.

This pesticide is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

Precautionary Statements

Hazards to Humans and Domestic Animals

CAUTION

Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Harmful if inhaled. Avoid contact with skin, eyes or clothing, and avoid breathing vapor. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

First Aid

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for further treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-888-963-8471 for emergency medical treatment information.

User Safety Requirements

Follow manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- User should remove clothing/ PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- User should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

All handlers must wear:

- long-sleeved shirt and long pants
- socks and shoes
- chemical-resistant gloves (such as those made out of any waterproof material, selection category A).

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.